

Laser additive manufacturing of customized prosthetics and implants for biomedical applications

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15.1 Introduction

Personalization by tailoring a product to serve a specific need has become an area of great interest in the medical industry. Instead of using standard products that are designed to accommodate many, an individual approach offers much potential for the optimal treatment of a disease.

Today, many biomedical applications are based on personalized products, such as prosthetics and implants that replace lost limbs or bone, or that rebuild a joint function specific to a patient's situation. Other examples are bone augments or partial bone replacements, limb diaphysis components, or full anatomic replicas.

While advancements in the digitization and processing of patient data have greatly facilitated this development over the past decade, one key enabler was progress in the production technology of additive manufacturing (AM), such as laser AM (LAM). It allows for the layer-by-layer production of prosthetics and implants with complex anatomic surface shapes made of a variety of biocompatible or load-bearing materials. Because of the digital process chain, it is feasible to apply patient-specific and custom-made designs to optimally treat the medical condition.

This chapter gives an overview of the potential of LAM for use in customized medical applications, which materials are available, and how the process chain works.

15.2 Biocompatible materials and properties

Biocompatibility is generally viewed as the lack of interaction of a material with living tissue. The biocompatibility of a material is evaluated according to a set of standards defined in ISO 10993 [1]. Today, a broad range of materials that are processed by LAM fulfill this property and can be used to fabricate medical devices. Which material is best suited for each specific application is determined during the product development process, based on a list of requirements. Many variables come into play, such as purpose of use, mechanical and chemical properties, geometric boundaries, and cost.

The following gives a general overview of LAM materials that are in production today or are in development and that offer great future potential for use in medical applications.

15.2.1 Polymeric materials

15.2.1.1 Polyamide

Polyamide (PA) is today the most widely used synthetic LAM material for medical devices. A variety of medical applications have been developed using PA12. Processed by selective laser sintering, PA12 is biocompatible according to EN ISO 10993-1 and U.S. Pharmacopeia classification VI. It is suitable for heat sterilization at 121°C [2].

15.2.1.2 Polyaryletherketones

Polyaryletherketones are thermoplastic polymers with high temperature stability, high mechanical strength, and high chemical resistance. They have been used in biomedical applications of trauma, orthopedic, and spinal implants since the 1980s [3]. LAM technology to process polyetheretherketone is commercially available from EOS [4]. Polyetherketoneketone, another polyaryletherketone material, has received US Food and Drug Administration approval [5]. The technology to process this material is offered by Oxford Performance Materials.

15.2.1.3 Polylactide

Polylactides are a polymeric material with promising potential because they are bioresorbable. A composite of a polylactide and ceramic β -tricalcium phosphate (β -TCP) can be processed with selective laser melting to achieve up to 99.5% density [6]. Further studies of β -tricalcium phosphate and poly(D,L)-lactide showed the feasibility of the production of interconnected porous structures with the selective laser melting process [7].

15.2.1.4 Polycaprolactone

Polycaprolactone is another biodegradable polymer that can be processed by selective laser sintering. Scaffolds for repairing skeletal defects were produced successfully [8].

15.2.2 Metallic materials

15.2.2.1 Cobalt–chromium

Cobalt–chromium (CoCr) alloys have a long history of use in dental applications. In orthopedics they come into play for joint replacement and fixation of bone fractures. LAM of CoCr alloys has been well studied and creates manufactured parts with a density more than 99.9% [9]. The in vitro corrosion resistance of additively manufactured CoCr parts is reported to be superior to CoCr cast material [9,10].

15.2.2.2 *Commercially pure titanium*

Commercially pure titanium (cpTi) and its alloys Ti-6Al-4V and Ti-6Al-7Nb are biocompatible materials and are widely used to treat osseous defects. While cpTi offers good ductility, a higher stiffness and fatigue resistance can be achieved by alloying titanium. The general downside of using metallic materials to treat osseous defects is the difference in the stiffness of the metal compared with that of bone and the resulting stress shielding effect. The mechanical shielding of the bone can cause bone degradation and consequently implant failure. Compared with stainless steel or CoCr, titanium has about half the elastic modulus (around 110 GPa) and thus causes a lower stress shielding effect.

Conditioned by the stable TiO₂ layer that forms on the surface, titanium implants are osseointegrative and can be used for cement-free implant devices. Bone growth onto the implant surface creates secondary stability after the press-fit primary stability decreases. Titanium and its alloys are not used directly as articulation surfaces in joints unless they are coated to reduce wear.

Additive manufacturing of titanium alloys has been well studied because of its numerous applications in the medical industry. Because of the challenge it poses in conventional processes such as cutting or casting, the additive manufacturing of titanium offers great potential.

Compared with casted cpTi, the material showed similar wear characteristics when processed by LAM and offered better wear resistance, finer grain size, and superior microhardness [11]. Processing of porous cpTi structures is feasible and offers a variety of applications in the medical industry [12].

15.2.2.3 *Titanium alloy Ti₆Al₄V*

The titanium alloy Ti-6Al-4V is widely used in joint replacement because of its good mechanical properties. This versatile material offers high fatigue resistance, good biocompatibility, and osseointegrativity.

LAM-processed Ti-6Al-4V forms a predominant martensitic-like microstructure. As a result of the high temperature gradient and fast cooling, the as-built material has very high strength (yield strength and ultimate tensile strength typically are >1,000 MPa); however, at the same time it is brittle with a relatively low ductility of elongation (5%) [13]. Furthermore, considerably high residual stresses remain in the part and can cause part deformation [14,15]. A heat treatment after processing is used to relax stresses and can raise elongation to above 10%, which is required for medical applications, according to current standards for the material.

Several studies have looked at the bone regeneration performance of LAM Ti-6Al-4V. Surface treatment with acids, alkalis, and an anodizing heat treatment was demonstrated to be feasible for the biofunctionalization of LAM Ti-6Al-4V and improved its bone regeneration performance [16]. A method for functionalizing the surface of LAM Ti-6Al-4V with bioactive compounds for drug delivery after implantation was successfully developed [17].

15.2.2.4 *Nickel titanium*

Nickel titanium, also known as nitinol, is a pseudo-elastic material. Because of a phase transformation during deformation, this alloy displays a high recovery strain. After a would-be plastic deformation of the material, heating causes the part to reset to its previous geometry; hence a shape memory exists. This feature can be used as a controlled function of medical products that is initiated by body heat, as in self-expanding stents.

LAM-processed nitinol shows good biocompatibility [18]. The process parameters not only influence the surface structure and topography but also ion release. Shape recovery of up to 3% was demonstrated for LAM-processed nitinol. Further, the process parameters can locally influence the behavior and tailor the pseudo-elastic effect [19]. Porous structures of nitinol with a porosity up to 88% and lattice material with a density up to 99.8% were fabricated [20].

15.2.2.5 *Other titanium alloys*

A preliminary study of LAM of the titanium alloy Ti-6Al-7Nb displayed the general feasibility of the process and established the importance of a heat treatment after processing [21]. Depending on the heat treatment parameters, the microstructure could be specifically altered and influenced. Several coatings on LAM Ti-6Al-7Nb samples were tested in an in vivo rat model [22]. The animal study showed no inflammatory reaction for plain, hydroxyapatite, and SiO₂–TiO₂ coatings and suggests that the LAM-processed alloy is well tolerated biologically. LAM processing of the titanium alloy Ti-24Nb-4Zr-8Sn was used to fabricate scaffolds. The solid struts yielded a density up to 99.3% [23].

15.2.2.6 *Tantalum*

Because of the development of a conventional process to create tantalum sponges, the material came into focus around the year 2000 and found its way into many applications for repairing bone defects. With characteristics similar to titanium, tantalum can be used for cement-free applications at the bone–implant interface. The feasibility of its use in LAM has been successfully demonstrated [24]. Porous tantalum structures were produced and mechanical test results were in the range of cancellous bone. Another study in a rat segmental bone defect model in vivo demonstrated good osseointegration and biomechanical performance.

15.2.2.7 *Precious metals*

Precious metals such as gold and platinum can be processed well via LAM [25,26]. Because of the high investment cost and difficult management of powder waste, typically only small to medium-sized machines are used for processing.

15.2.2.8 *Stainless steel*

Stainless steel was among the first metals to be used in laser melting processes using only a single component material. Today, LAM of several biocompatible stainless steel alloys, such as 304 or 316L, are readily available on the market.

15.2.2.9 *Magnesium and its alloys*

Magnesium is a biodegradable material and because of its load-bearing property has a large range of potential medical applications. Initial attempts to process this highly reactive material using LAM were done by melting single tracks of pure magnesium [27,28]. To overcome the difficulty in meeting the narrow window between melting and boiling during the process, the concept of an overpressure LAM machine and the use of magnesium alloys was proposed [29]. The alloy AZ91 was processed to a density of up to 99% [30]. Pure magnesium was later processed to a lattice with a 600- μm pore size [31]. Today, the outgassing of alloying elements and the resulting high residual stresses are challenges for fabricating solid parts and make the material and its alloys the subject of ongoing research and development efforts [32].

15.2.3 *Ceramics*

Ceramics are bioinert materials with high application potential. Because of their hardness and resistance to wear, ceramics show excellent behavior in tribological systems such as joint bearings. Wear debris is regarded as less critical compared with plastic or metal abrasion, which can lead to infection and consequently implant failure. In general, biodegradable ceramics can also be used as a bone substitute.

The challenge in LAM of ceramics is to fabricate dense and crack-free parts. High melting points cause steep temperature gradients, which lead to residual stresses and crack formation. Technology and process developments are ongoing, such as preheating the material to reduce temperature gradients [33].

15.2.4 *Cellular structures*

Cellular structures are omnipresent as a building block in nature. Adapting their principles into product design can optimize resulting properties, such as the weight-to-strength ratio, energy absorption, and heat transfer [34].

In medical devices, cellular structures can be used to copy biomimetic features. In tissue engineering, additively manufactured scaffolds are used as a substrate matrix for cells. The mechanical properties or appearance of prosthetics and orthotics can be influenced to a desired state. Today, cellular structures made by LAM of metallic materials are widely used in the field of endoprostheses. A foam-like porous structure similar to trabecular bone is manufactured directly on an implant. The application of such open porous structures at the bone–implant interface can facilitate permanent bone on- and ingrowth and provide secondary stability for cement-free cases.

No secondary coating process is needed to provide the required rough surface properties on implants. Resulting pore sizes of around 0.5 mm can be completely bridged by osteoblast cells [35].

Common approaches for the design of cellular structures are unit cell-based periodic designs that are arranged in two- or three-dimensional (3D) arrays [36], as stochastic or randomized structures [37], or as complex surfaces [38]. The characteristics of cellular structures are influenced by several parameters such as geometry, material, and postprocessing and are typically described in their respective relative or specific values [39]. The resulting properties of such cellular structures can be specifically designed to meet desired requirements. For example, by reducing the apparent density, the Young's modulus can be reduced to that of cancellous bone, which offers potential for reducing the stress shield effect of implants.

Highly filigreed cellular structures are manufactured by pointwise exposition of a powder instead of the conventional scanning strategy of contour and core. Here, the minimal lattice diameter or wall thickness correlates with the resolution of the weld bead. To avoid issues with large data sets that result from the surface representation of such cellular structures, data processing in point clouds or layer format is sometimes applied.

Many studies focused on process development and the characterization of resulting cellular structures for a variety of materials [40–42]. The effect of applying cellular structures at the bone–implant interface also showed great potential [43,44].

Further treatment of the cellular structure with a biomaterial can tap a significant potential for medical applications. In an *in vivo* study, high-molecular-weight bone morphogenetic proteins were applied into the titanium cellular structure to enhance bone regeneration. After 4 weeks, full regeneration of the segmental bone defect, including the medullary canal and cortex, was observed [45] (Fig. 15.1).

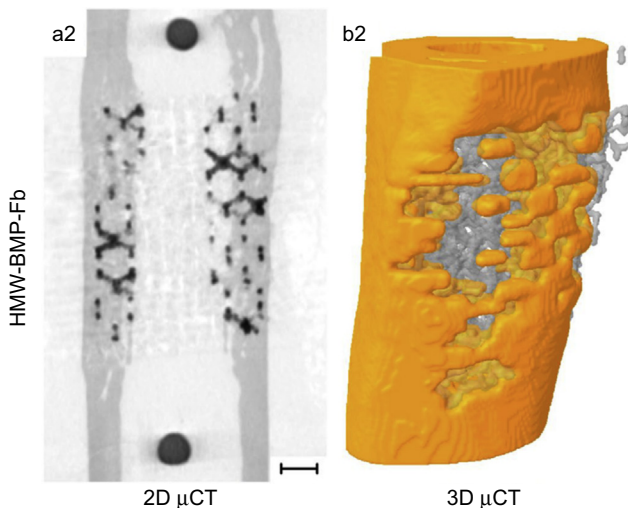


Figure 15.1 Full bone regeneration with the addition of a biomaterial to the porous scaffold [45]. *HMW-BMP-Fb*, high molecular weight fibrinogen with bone morphogenetic proteins.

15.3 Process chain for customized prosthetics and implants

15.3.1 Product requirements

The main goal of the process chain for customized prosthetics and implants is to satisfy the customers' — that is, the patients' — needs by transferring the requirements into a product (see Fig. 15.2). Such requirements are constrained by each individual clinical case and the patient's situation. Decisions on a multitude of options such as function, geometry, material, and interfaces have to be made throughout the development of the product.

15.3.2 Design process

The conventional design process for series prosthetics and implants relies on a computer-aided design (CAD) approach. Based on an average body geometry, a product is developed to serve a function and is subdivided into different sizes to cover a large quantity of the population.

The design process for customized medical devices, however, is based on a reverse-engineering principle. The initial position for the process is the individual patient's clinical situation, which has to be recorded and transferred into a virtual model. Based on this unique data set, a unique product is designed to meet the patient's need.

Advancements in imaging technology enable such applications. Imaging technology used today includes 3D surface scanning or volume scanning techniques such as computed tomography (CT) and magnetic resonance imaging (MRI). For prosthetics or orthodontics, a 3D surface scan of the region of interest can be sufficient. This scan is either performed directly on the patient or indirectly using an impression.

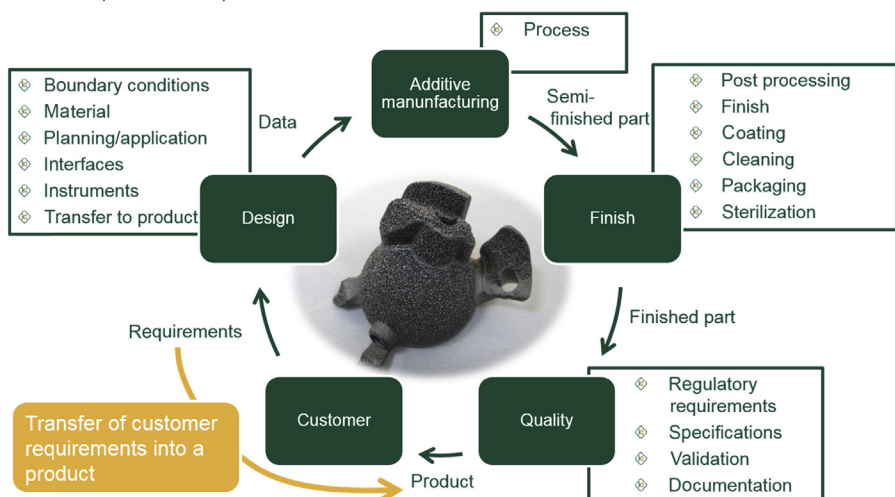


Figure 15.2 Challenges of individualization in the additive manufacturing of medical products.

Volume scanning techniques such as CT or MRI capture a stack of two-dimensional slices of the patient's body. The imaging data are gathered from different angles and then processed by a software algorithm. This allows a virtual 3D model to be reconstructed that accurately reflects the patient's situation. For CT and MRI, the process of segmentation yields a model in which tissue type can be distinguished and classified.

For customized endoprostheses, the subsequent design process is highly interdisciplinary. Clinicians and design engineers, in close collaboration, make use of the resulting model as well as the underlying clinical situation to plan the implant and decide on its features, such as type, positioning, bone resection lines, and type of fixation. Based on this information, a design is derived and, if necessary, iterated and optimized.

Processing the virtual model poses a significant challenge for design engineers because of its complex anatomic shape, represented by free-form surfaces. Conventional CAD software can be used only conditionally to derive a solution. A set of software tools has yet to be procured that allows for complex surface modeling or the design of osseointegrative cellular structures. Moreover, the design of customized endoprostheses not only includes the implant but also incorporates surgery planning, consisting of resection lines, patient-specific instruments, and screw positioning.

The design space and medical boundary conditions have to be considered during the design process, but the AM process itself and subsequent finishing operations also have to be taken into account. Best results are achieved by training designers in AM and establishing a continuous process of knowledge transfer between design and production departments. By implementing such manufacturing knowledge into the design process, customized implants can be fabricated correctly the first time, without the need for prototyping or testing. During the design phase, building directions can be defined, surfaces for support structures described, and additional material stock for postprocessing included.

In general, the nature of the product calls for reducing risk as much as possible. One approach to achieve this is to combine the customized implant with standard components. Using predefined implant connection interfaces, larger defects can be repaired by a combination of standard and modular implant systems. Such interfaces can be incorporated well into the design of the custom components. Instead of conventional postprocesses such as milling or turning, interfaces can be additively manufactured, reducing the overall production effort. Templates for interfaces of sockets, screw threads, or bayonet joints can be established and validated for use.

15.3.3 Production process

The production of medical devices is an extremely regulated process, with requirements defined by higher-level regulatory agencies. Technologically, the actual additive production process does not differ from that used for nonmedical products. Nonetheless, for conformity, the additive production and subsequent processes require the application of good manufacturing practices to ensure product quality. The implementation of such guidelines for LAM has not yet ultimately been established in industry and is up to interpretation by each manufacturer. However, the first industry standards,

such as the ASTM specification for powder bed fusion of the titanium alloy Ti-6Al-4V [46], have been approved and are ready for adoption by the industry. In general, the process chain for customized AM of medical devices should aim for specified and validated production, allowing for complete traceability and assurance of the quality of all its products.

15.3.4 Postprocessing

The postprocessing of customized products has to be applied in such a way that previously determined product requirements are met. The selection of postprocesses depends on the design, material, and LAM process. Metallic materials usually require a heat treatment to reduce residual stress and meet the material specifications.

Customized products for the purpose of implantation need to be sterile at the end of production. Endoprostheses with cellular structures especially have to be thoroughly cleaned to remove any adhering powder particles or residues, such as contamination from the grinding paste or the cooling liquid from computer numerical control processes. Typical methods are shot peening, ultrasonic cleaning, and applicable sterilization processes.

15.4 Applications

15.4.1 Endoprostheses

Endoprostheses are implants that remain in the body and restore the natural function of defective bones or joints. Bone and joint replacements have many requirements because of their load-bearing nature.

The majority of metallic LAM implants today are produced from the titanium alloy Ti-6Al-4V and used for cement-free applications. Here, the implant fixture is not achieved using polymethylmethacrylate (so-called bone cement). Instead, a porous structure at the bone–implant interface facilitates osseointegration and, after losing primary stability through press-fit insertion, secondary stability is achieved.

The need for custom-made implants typically only arises for larger or highly complex defects that cannot be treated with standard products. Such severe cases include trauma, revision of implants, or tumors. Compared with series implants, the share of such customized endoprostheses is negligible.

Today, LAM technology is used to fabricate a variety of products, both custom-made and series products, for application during surgery. Several remarkable applications are presented in the following subsections.

15.4.1.1 Patient-specific surgical guides

The implantation of series or individual implants can be facilitated through custom-made instruments. Such patient-specific instruments (PSIs) are used to objectively identify anatomic landmarks for surgical guidance. Based on preoperative patient

imaging data (CT, MRI), PSIs are custom designed to fit to a unique position and thus orient a drilling or cutting guide to its desired position (see Fig. 15.4). Though a controversial issue among surgeons, claimed benefits are improved implant alignment, reduction of tissue loss, less instrument inventory, and shorter operating time [47].

Since there is low mechanical stress on PSIs during application, a biocompatible polymeric material can be used, such as PA, by selective laser sintering. To avoid plastic debris during application, PSIs can include a metallic cover at the drilling or sawing guide interface.

15.4.1.2 Hip implants

A LAM-fabricated revision hip cup for series application was developed using the titanium alloy Ti-6Al-4V (see Fig. 15.3). The osseointegrative structure at the bone–implant interface facilitates bone ingrowth and secondary stability [48].

Depending on the resection lines of the hip, there is a variety of clinical cases for custom-made partial hip replacements [49]. The LAM-produced part typically replaces the defective bone. The actual joint function is restored using a standard hip cup-and-stem system that is fixated into the custom-made part. Examples of a PSI drilling guide and a custom-made partial hip replacement implant with osseointegrative surface modification are displayed in Figs. 15.4 and 15.5, respectively.



Figure 15.3 MUTARS revision hip cup.
Courtesy of Implantcast GmbH.



Figure 15.4 Patient-specific instrument drilling guide for a partial hip replacement. Courtesy of Implantcast GmbH.



Figure 15.5 Laser additively manufactured custom-made partial hip replacement. Courtesy of Implantcast GmbH.

While much effort is made to design and fabricate to match the implant exactly to the patient's bone model, the in situ situation can be different. Larger defects especially can involve the revision of implants or bone grafts that alter the bone surface. This can ultimately cause misalignment of the custom implant. However, the clinical relevance of the positional accuracy of such custom-made implants is still unclear [50].

A methodology for simulating and designing patient-specific hip stems has been presented [51]. The custom design allows for an optimal load transfer and biomechanical situation. The production of customized hip stems was studied using the additive manufacturing process of electron beam melting with the material Ti-6Al-4V [52]. While commercially viable, the study pointed out that an appropriate postprocessing surface finish is indispensable to achieve a high fatigue limit.

15.4.1.3 Knee implants

Today, customized knee endoprostheses for primary implantation are offered as mass customized service. Not LAM but an indirect manufacturing technology is reportedly used [53]. A wax pattern of the customized knee implant is additively manufactured and then used for investment casting. Clinically, custom-made partial knee replacements show good promise [54].

The process chains for custom-made knee replacements using LAM as a direct manufacturing technology are still being developed and have not been publically announced. Because of the complexity of the geometry of the articulating surface of the knee, LAM has much potential as a viable production technology in the future. An initial study showed the successful application of a partial knee arthroplasty for a large bone and joint defect [55] (Figs. 15.6 and 15.7, respectively).

15.4.1.4 Spinal implants

Interbody fusion cages are used for spinal arthrodesis. Their relatively small size, complex form, and need for surface modification for osseointegration make LAM a viable method for series production today. An evaluation of the structural and mechanical



Figure 15.6 Three-dimensional design of a knee implant [55].

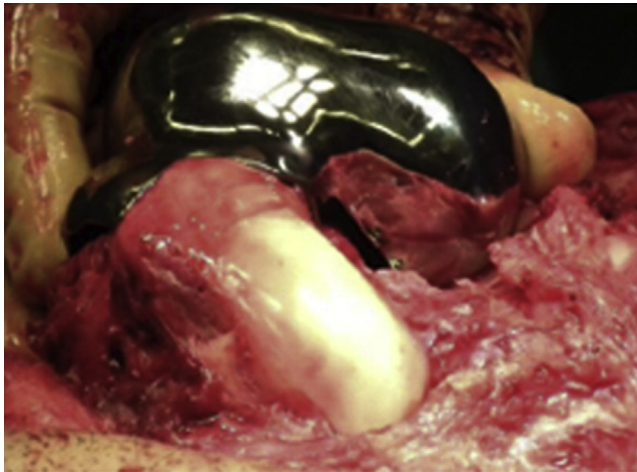


Figure 15.7 Custom-made lateral femoral hemiarthroplasty (Stuys et al. [55]).

properties of such a spinal implant produced by LAM showed good results [12]. Introducing a porous structure to reduce the specific Young's modulus allows for lower stress shielding and promises a better clinical outcome.

The idea for a process chain to produce patient-specific intervertebral disc implants was proposed [56]. Based on imaging data, bone landmarks were identified and used to design the disc surface. An artificial ball-and-socket joint was designed and positioned with regard to the biomechanical analysis of the patient (see Fig. 15.8).



Figure 15.8 Intervertebral disc implant made of Ti-6Al-4V [56].

15.4.1.5 Upper extremities

Customized joint and partial bone replacements of the humerus, radius, and ulna are facilitated by the LAM process chain and are in production today. But LAM also offers great potential for the treatment of other parts of the upper extremities, such as the complex carpal bones. A method for scaphoid reconstruction using titanium templates was developed [57]. Based on patient imagery, templates are fabricated to fit to surfaces of the proximal and distal scaphoid poles in order to achieve a defined relative position after resection. An in vitro study showed that better preoperative planning can largely improve the outcome.

The symmetry of the bone structure of the human body can benefit and facilitate the problem-solving process. This came into play for the treatment of a shoulder blade affected by a tumor. The imaging data from the area of interest was not fit for reconstruction. Hence, a virtual model of the healthy left side was created, mirrored, and used as the basis for the implant design. The resulting full anatomic scapula replacement for the right side was made by LAM of Ti-6Al-4V (Fig. 15.9).

15.4.1.6 Chest wall

Several procedures for rigid reconstruction of the chest wall are in use today, such as plates, meshes, and polymer composites. However, they may not restore the full function of the chest wall and can limit stability [58].

Large anterior chest wall defects have recently been treated successfully using customized LAM implants. The customized sternal implant shown in Fig. 15.10 was used to reconstruct the chest wall, which was resected because of a tumor [59]. The artificial sternum was made from Ti-6Al-4V. The reported benefits are time savings and rigid reconstruction of the whole sternum without any complications.



Figure 15.9 Full anatomic scapula replacement.
Courtesy of Implantcast GmbH.

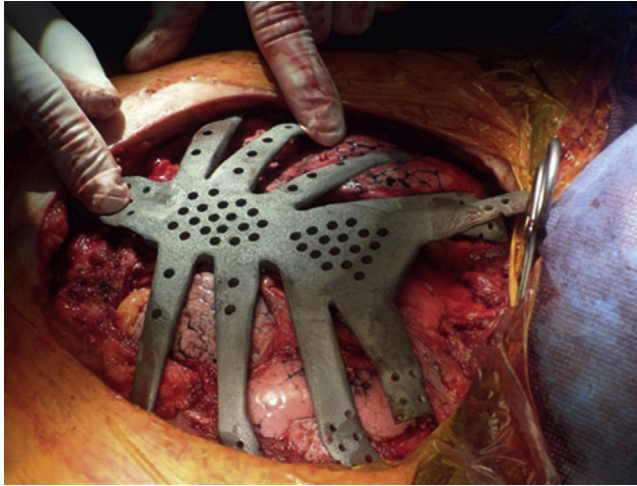


Figure 15.10 Customized sternal implant [59].

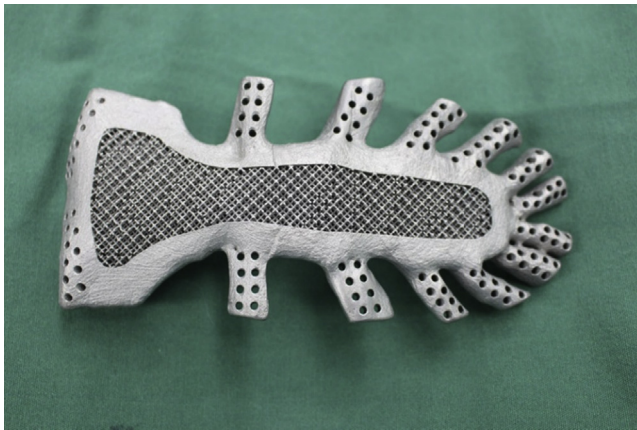


Figure 15.11 Custom-made titanium sternal replacement (Tang Du Hospital, Xi'an, China) [58].

Another custom-made sternal replacement fabricated from a titanium alloy replaced a resected chest bone after cancer [58] (see Figs. 15.11 and 15.12). The implant protects the patient's heart and other organs.

15.4.1.7 Other customized endoprotheses

Looking beyond LAM, other AM technologies are in use today to satisfy patients' needs. A patient-specific foot joint implant was developed based on the simulation of motion. The implant was produced by investment casting based on a printed fused deposition model [60].

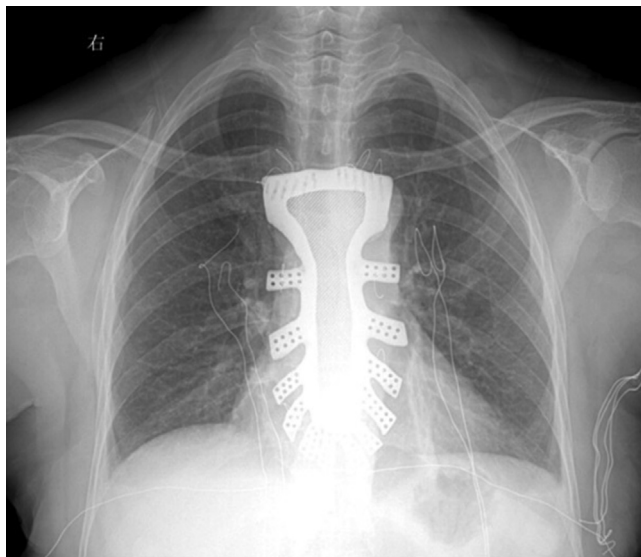


Figure 15.12 Radiograph of the inserted sternal replacement (Tang Du Hospital, Xi'an, China) [58].

A custom-made heel bone made from titanium was used to treat a cancer patient (see Figs. 15.13 and 15.14). It was produced with an electron beam melting process and implanted in Australia in 2014.

15.4.2 *Prosthetics and orthotics*

Prosthetics and orthotics are externally applied to replace, modify, or support limbs or other bodily functions. AM has played an important role in this field for many years



Figure 15.13 Custom-made heel implant (St. Vincent's Hospital, Melbourne, Australia).

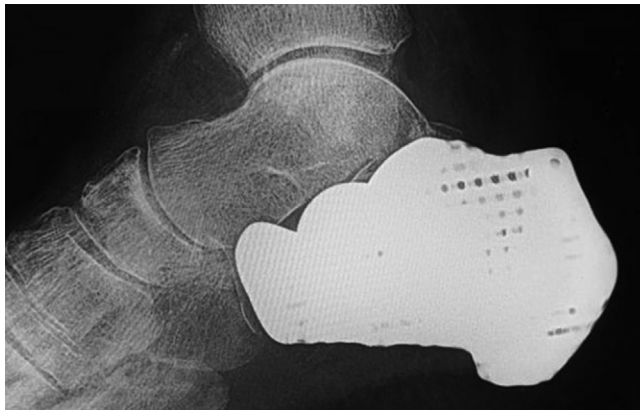


Figure 15.14 Radiograph of a custom-made heel implant (St. Vincent's Hospital, Melbourne, Australia).



Figure 15.15 Artificial limb cladding with a cellular surface structure. Courtesy of 3D Systems, Inc.

and has become one of the standard processes for fabrication of, for example, customized hearing aids and artificial limbs (see Fig. 15.15).

Advancements in 3D imaging create further potential in this field. Typically, imprints and molds are used to re-create a patient's situation. These steps may become obsolete. Camera technology and software allow the outer surface shape of body parts to be scanned directly. The image information is reconstructed into a virtual 3D model used to design the product. AM technology is then used to transfer the designed solutions into an application. This process chain allows for the optimal fit of medical devices and subsequent fulfillment of their desired function.

In a pilot study, a methodology and workflow were developed to build a customized wrist orthosis [61]. Orbital prosthesis are created by stereolithography to restore a natural look [62]. AM also is available for the mass customization of products such as shoe insoles to correct malposition [63]. Traditionally, such customized products require intensive manual work. The shift to a digital process chain with AM as the production technology opens great potential for savings in costs and time.

15.5 Summary

LAM of customized prosthetics and implants has become an essential part of the treatment of certain medical conditions. Such tailored products can meet a patient's needs without compromise.

A broad range of biocompatible materials for LAM processes is available today. This allows the requirements of a multitude of applications to be fulfilled. With future developments along the whole process chain, including in manufacturing technologies and data preparation, further improvement can be expected for customized solutions that enhance even more a patient's situation.

References

- [1] ISO 10993–1:2010, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing in the Risk Management Process, 2010.
- [2] EOS GmbH, Material Properties Polyamide, 12, 2010, p. 2.
- [3] S.M. Kurtz, J.N. Devine, PEEK biomaterials in trauma, orthopedic, and spinal implants, *Biomaterials* 28 (2007) 4845–4869, <http://dx.doi.org/10.1016/j.biomaterials.2007.07.013>.
- [4] EOS GmbH, EOS PEEK HP3, 2015.
- [5] FDA, FDA 510k Clearance Oxford Medical PEKK, 2013. http://www.accessdata.fda.gov/cdrh_docs/pdf12/K121818.pdf.
- [6] S. Hoeges, M. Lindner, H. Fischer, W. Meiners, K. Wissenbach, Manufacturing of bone substitute implants using selective laser melting, *Analysis* (2009) 2230–2234.
- [7] M. Lindner, S. Hoeges, W. Meiners, K. Wissenbach, R. Smeets, R. Telle, et al., Manufacturing of individual biodegradable bone substitute implants using selective laser melting technique, *Journal of Biomedical Materials Research – Part A* 97 A (2011) 466–471, <http://dx.doi.org/10.1002/jbm.a.33058>.

- [8] A. Mazzoli, C. Ferretti, A. Gigante, E. Salvolini, M. Mattioli-Belmonte, Selective laser sintering manufacturing of polycaprolactone bone scaffolds for applications in bone tissue engineering, *Rapid Prototyping Journal* 21 (2015) 386–392, <http://dx.doi.org/10.1108/RPJ-04-2013-0040>.
- [9] B. Vandenbroucke, J.-P. Kruth, Selective laser melting of biocompatible metals for rapid manufacturing of medical parts, *Rapid Prototyping Journal* 13 (2007) 196–203, <http://dx.doi.org/10.1108/13552540710776142>.
- [10] F. Alifui-Segbaya, P. Foley, R.J. Williams, The corrosive effects of artificial saliva on cast and rapid manufacture-produced cobalt chromium alloys, *Rapid Prototyping Journal* 19 (2013) 95–99, <http://dx.doi.org/10.1108/13552541311302941>.
- [11] H. Attar, K.G. Prashanth, A.K. Chaubey, M. Calin, L.C. Zhang, S. Scudino, et al., Comparison of wear properties of commercially pure titanium prepared by selective laser melting and casting processes, *Materials Letters* 142 (2015) 38–41.
- [12] C.Y. Lin, T. Wirtz, F. LaMarca, S.J. Hollister, Structural and mechanical evaluations of a topology optimized titanium interbody fusion cage fabricated by selective laser melting process, *Journal of Biomedical Materials Research – Part A* 83 (2007) 272–279, <http://dx.doi.org/10.1002/jbm.a.31231>.
- [13] L.E. Murr, S.A. Quinones, S.M. Gaytan, M.I. Lopez, A. Rodela, E.Y. Martinez, et al., Microstructure and mechanical behavior of Ti-6Al-4V produced by rapid-layer manufacturing, for biomedical applications, *Journal of the Mechanical Behavior of Biomedical Materials* 2 (2009) 20–32, <http://dx.doi.org/10.1016/j.jmbbm.2008.05.004>.
- [14] C. Over, Generative Fertigung von Bauteilen aus Werkzeugstahl X38CrMoV5-1 und Titan TiAl6V4 mit “Selective Laser Melting.”, Shaker, Aachen, 2003.
- [15] M. Munsch, Reduzierung von Eigenspannungen und Verzug in der laseradditiven Fertigung, Cuvillier, Göttingen, 2013.
- [16] S. Amin Yavari, J. van der Stok, Y.C. Chai, R. Wauthle, Z. Tahmasebi Birgani, P. Habibovic, et al., Bone regeneration performance of surface-treated porous titanium, *Biomaterials* 35 (2014) 6172–6181, <http://dx.doi.org/10.1016/j.biomaterials.2014.04.054>.
- [17] J. Vaithilingam, S. Kilsby, R.D. Goodridge, S.D.R. Christie, S. Edmondson, R.J.M. Hague, Functionalisation of Ti6Al4V components fabricated using selective laser melting with a bioactive compound, *Materials Science and Engineering: C* 46 (2015) 52–61, <http://dx.doi.org/10.1016/j.msec.2014.10.015>.
- [18] T. Habijan, C. Haberland, H. Meier, J. Frenzel, J. Wittsiepe, C. Wuwer, et al., The biocompatibility of dense and porous Nickel-Titanium produced by selective laser melting, *Materials Science and Engineering: C* 33 (2013) 419–426, <http://dx.doi.org/10.1016/j.msec.2012.09.008>.
- [19] T. Bormann, R. Schumacher, B. Müller, M. Mertmann, M. Wild, Tailoring selective laser melting process parameters for NiTi implants, *Journal of Materials Engineering and Performance* 21 (2012) 2519–2524, <http://dx.doi.org/10.1007/s11665-012-0318-9>.
- [20] M. de Wild, T. Schollbach, R. Schumacher, E. Schkommodau, T. Bormann, Effects of laser parameters and scanning strategy on structural and mechanical properties of 3D NiTi implants fabricated with selective laser melting, *Biomedical Engineering/Biomedizinische Technik* 58 (2013) 9–10, <http://dx.doi.org/10.1515/bmt-2013-4088>.
- [21] T. Sercombe, N. Jones, R. Day, A. Kop, Heat treatment of Ti-6Al-7Nb components produced by selective laser melting, *Rapid Prototyping Journal* 14 (2008) 300–304, <http://dx.doi.org/10.1108/13552540810907974>.

- [22] H. Rotaru, G. Armencea, D.I. Spîrchez, C. Berce, T.E. Marcu, In vivo behavior of surface modified Ti 6 Al 7 Nb alloys used in selective laser melting for custom-made implants. A preliminary study, *Romanian Journal of Morphology and Embryology* 54 (2013) 791–796.
- [23] Y.J. Liu, X.P. Li, L.C. Zhang, T.B. Sercombe, Processing and properties of topologically optimised biomedical Ti – 24Nb – 4Zr – 8Sn scaffolds manufactured by selective laser melting, *Materials Science and Engineering: A* 642 (2015) 268–278.
- [24] R. Wauthle, J. van der Stok, S. Amin Yavari, J. Van Humbeeck, J.-P. Kruth, A.A. Zadpoor, et al., Additively manufactured porous tantalum implants, *Acta Biomaterialia* 14 (2014) 217–225, <http://dx.doi.org/10.1016/j.actbio.2014.12.003>.
- [25] M. Khan, P. Dickens, Selective laser melting (SLM) of gold (Au), *Rapid Prototyping Journal* 18 (2012) 81–94, <http://dx.doi.org/10.1108/13552541211193520>.
- [26] D. Zito, A. Carlotto, A. Loggi, P. Sbornicchia, D. Bruttomesso, S.A. Progold, Definition and Solidity Idity of Gold and Platinum Jewels Produced Using Selective Laser Melting SLM™ Technology, 2015.
- [27] C.C. Ng, Selective laser sintering of magnesium powder for fabrication of porous structures, in: 17th International Conference on Advanced Laser Technologies, Antalya, 2009.
- [28] C.C. Ng, M.M. Savalani, H.C. Man, I. Gibson, Layer manufacturing of magnesium and its alloy structures for future applications, *Virtual and Physical Prototyping* 5 (2010) 13–19, <http://dx.doi.org/10.1080/17452751003718629>.
- [29] M. Gieseke, C. Noelke, S. Kaierle, V. Wesling, H. Haferkamp, Selective laser melting of magnesium and magnesium alloys, in: *Magnesium Technology, 2013*, John Wiley & Sons, Inc., Hoboken, NJ, USA, 2013, pp. 65–68, <http://dx.doi.org/10.1002/9781118663004.ch11>.
- [30] L. Jauer, W. Meiners, R. Poprawe, Selective laser melting of biodegradable metals, *European Cells and Materials* 26 (2013) 21.
- [31] J. Matena, S. Petersen, M. Gieseke, M. Teske, M. Beyerbach, A. Kampmann, et al., Comparison of selective laser melted titanium and magnesium implants coated with PCL, *International Journal of Molecular Sciences* 16 (2015) 13287–13301, <http://dx.doi.org/10.3390/ijms160613287>.
- [32] M. Gieseke, T. Kiesow, C. Nölke, S. Kaierle, H.J. Maier, H. Haferkamp, Selektives Laserstrahl-schmelzen von Magnesium und Magnesiumlegierungen, *Rapid Technologies*, Erfurt, 2015.
- [33] Q. Liu, Y. Danlos, B. Song, B. Zhang, S. Yin, H. Liao, Effect of high-temperature pre-heating on the selective laser melting of yttria-stabilized zirconia ceramic, *Journal of Materials Processing Technology* 222 (2015) 61–74.
- [34] L.J. Gibson, M.F. Ashby, *Cellular Solids: Structure and Properties*, second ed., Cambridge University Press, Cambridge, U.K, 1999.
- [35] P.H. Warnke, T. Douglas, P. Wollny, E. Sherry, M. Steiner, S. Galonska, et al., Rapid prototyping: porous titanium alloy scaffolds produced by selective laser melting for bone tissue engineering, *Tissue Engineering Part C, Methods* 15 (2009) 115–124, <http://dx.doi.org/10.1089/ten.tec.2008.0288>.
- [36] L. Mullen, R.C. Stamp, W.K. Brooks, E. Jones, C.J. Sutcliffe, Selective Laser Melting: a regular unit cell approach for the manufacture of porous, titanium, bone in-growth constructs, suitable for orthopedic applications, *Journal of Biomedical Materials Research Part B Applied Biomaterials* 89B (2009) 325–334, <http://dx.doi.org/10.1002/jbm.b.31219>.

- [37] L. Mullen, R.C. Stamp, P. Fox, E. Jones, C. Ngo, C.J. Sutcliffe, Selective laser melting: a unit cell approach for the manufacture of porous, titanium, bone in-growth constructs, suitable for orthopedic applications. II. Randomized structures, *Journal of Biomedical Materials Research – Part B, Applied Biomaterials* 92 (2010) 178–188, <http://dx.doi.org/10.1002/jbm.b.31504>.
- [38] C. Yan, L. Hao, A. Hussein, P. Young, Ti-6Al-4V triply periodic minimal surface structures for bone implants fabricated via selective laser melting, *Journal of the Mechanical Behavior of Biomedical Materials* 51 (2015) 61–73, <http://dx.doi.org/10.1016/j.jmbbm.2015.06.024>.
- [39] O. Rehme, *Cellular Design for Laser Freeform Fabrication*, Cuvillier, Göttingen, 2010.
- [40] S.M. Ahmadi, G. Campoli, S. Amin Yavari, B. Sajadi, R. Wauthle, J. Schrooten, et al., Mechanical behavior of regular open-cell porous biomaterials made of diamond lattice unit cells, *Journal of the Mechanical Behavior of Biomedical Materials* 34 (2014) 106–115, <http://dx.doi.org/10.1016/j.jmbbm.2014.02.003>.
- [41] H. Attar, M. Calin, L.C. Zhang, S. Scudino, J. Eckert, Manufacture by selective laser melting and mechanical behavior of commercially pure titanium, *Materials Science and Engineering A* 593 (2014) 170–177, <http://dx.doi.org/10.1016/j.msea.2013.11.038>.
- [42] Y. Wang, Y. Shen, Z. Wang, J. Yang, N. Liu, W. Huang, Development of highly porous titanium scaffolds by selective laser melting, *Materials Letters* 64 (2010) 674–676, <http://dx.doi.org/10.1016/j.matlet.2009.12.035>.
- [43] J.E. Biemond, G. Hannink, N. Verdonchot, P. Buma, Bone ingrowth potential of electron beam and selective laser melting produced trabecular-like implant surfaces with and without a biomimetic coating, *Journal of Materials Science Materials in Medicine* 24 (2013) 745–753, <http://dx.doi.org/10.1007/s10856-012-4836-7>.
- [44] J. Matena, M. Gieseke, A. Kampmann, S. Petersen, H. Murua Escobar, K. Sternberg, et al., Characterisation of cell growth on titanium scaffolds made by selective laser melting for tissue engineering, *Biomedical Engineering/Biomedizinische Technik* 58 (2013) 9–10, <http://dx.doi.org/10.1515/bmt-2013-4047>.
- [45] J. van der Stok, M.K.E. Koolen, M.P.M. de Maat, S.A. Yavari, J. Alblas, P. Patka, et al., Full regeneration of segmental bone defects using porous titanium implants loaded with BMP-2 containing fibrin gels, *European Cells and Materials* 29 (2015) 141–153 (discussion 153–4).
- [46] ASTM F3001-14, Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion, 2014, <http://dx.doi.org/10.1520/F3001>.
- [47] L. Renson, P. Poilvache, H. Van den Wyngaert, Improved alignment and operating room efficiency with patient-specific instrumentation for TKA, *Knee* 21 (2014) 1216–1220, <http://dx.doi.org/10.1016/j.knee.2014.09.008>.
- [48] V. Seyda, M. Munsch, P. Scheinmann, C. Emmelmann, Laser additive manufacturing of modified implant surfaces with osseointegrative characteristics, *Physics Procedia* 12 (2011) 375–384, <http://dx.doi.org/10.1016/j.phpro.2011.03.048>.
- [49] M. Rudert, B.M. Holzapfel, H. Pilge, H. Rechl, R. Gradinger, Partial pelvic resection (internal hemipelvectomy) and endoprosthetic replacement in periacetabular tumors, *Operative Orthopädie und Traumatologie* 24 (2012) 196–214, <http://dx.doi.org/10.1007/s00064-012-0161-z>.
- [50] M. Baauw, G.G. van Hellemond, M.L. van Hooff, M. Spruit, The accuracy of positioning of a custom-made implant within a large acetabular defect at revision arthroplasty of the hip, *The Bone and Joint Journal* 97-B (2015) 780–785, <http://dx.doi.org/10.1302/0301-620X.97B6.35129>.

- [51] S. Rahmati, F. Abbaszadeh, F. Farahmand, An improved methodology for design of custom-made hip prostheses to be fabricated using additive manufacturing technologies, *Rapid Prototyping Journal* 18 (2012) 389–400, <http://dx.doi.org/10.1108/13552541211250382>.
- [52] M. Crons-kär, M. Bäckström, L.-E. Rännar, Production of customized hip stem prostheses — a comparison between conventional machining and electron beam melting (EBM), *Rapid Prototyping Journal* 19 (2013) 365–372, <http://dx.doi.org/10.1108/RPJ-07-2011-0067>.
- [53] A. Gregg, Perfect Knee Implants, Courtesy of a 3-D Printer, 2015. Washington Post, http://www.washingtonpost.com/business/capitalbusiness/surgeons-turn-to-printed-implants/2014/12/23/0d5c353e-8486-11e4-9534-f79a23c40e6c_story.html.
- [54] M.K. Demange, A. Von Keudell, C. Probst, H. Yoshioka, A.H. Gomoll, Patient-specific implants for lateral unicompartamental knee arthroplasty, *International Orthopaedics* (2015) 4–7, <http://dx.doi.org/10.1007/s00264-015-2678-x>.
- [55] B. Stuyts, G. Peersman, E. Thienpont, E. Van den Eeden, H. Van der Bracht, Custom-made lateral femoral hemiarthroplasty for traumatic bone loss: a case report, *Knee* (2015) 6–10, <http://dx.doi.org/10.1016/j.knee.2015.06.008>.
- [56] N. De Beer, A. Van Der Merwe, Patient-specific intervertebral disc implants using rapid manufacturing technology, *Rapid Prototyping Journal* 19 (2013) 126–139, <http://dx.doi.org/10.1108/13552541311302987>.
- [57] M. Haefeli, D.J. Schaefer, R. Schumacher, M. Müller-Gerbl, P. Honigmann, Titanium template for scaphoid reconstruction, *The Journal of Hand Surgery, European Volume* 40 (2015) 526–533, <http://dx.doi.org/10.1177/1753193414549008>.
- [58] W. Hipolite, Woman with the Metal Chest : Surgeons Implant World's First 3D Printed Titanium Sternum, 2015. *3DPrint.com*. <http://3dprint.com/79908/3d-printed-sternum-implant/>.
- [59] A. Turna, K. Kavakli, E. Sapmaz, H. Arslan, H. Caylak, H.S. Gokce, et al., Reconstruction with a patient-specific titanium implant after a wide anterior chest wall resection, *Interactive Cardiovascular and Thoracic Surgery* 18 (2014) 234–236, <http://dx.doi.org/10.1093/icvts/ivt408>.
- [60] S.C. Raghatate, A.M. Kuthe, T.R. Deshmukh, S.W. Dahake, Rapid prototyping-assisted fabrication of the customized metatarsophalangeal joint implant (SamKu): a case report, *Rapid Prototyping Journal* 20 (2014) 270–279, <http://dx.doi.org/10.1108/RPJ-08-2012-0077>.
- [61] D. Palousek, J. Rosicky, D. Koutny, P. Stoklásek, T. Navrat, Pilot study of the wrist orthosis design process, *Rapid Prototyping Journal* 20 (2013) 27–32, <http://dx.doi.org/10.1108/RPJ-03-2012-0027>.
- [62] J. Sun, Y. Xiong, X. Chen, J. Xi, Imperfect symmetry transform for orbital prosthesis modelling, *Rapid Prototyping Journal* 19 (2013) 180–188, <http://dx.doi.org/10.1108/13552541311312175>.
- [63] SOLS Systems. <http://www.sols.com/>, 2015.